

### **REMARKS**

The present remarks are in response to the Office Action of March 7, 2006. Claims 11, 12, and 24-26 are currently pending.

Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, the Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action, claims 11-12, and 24-26 were rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Pat. No. 4,795,794 (hereinafter "Winnik").

#### **Rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) in the alternative**

Before discussing the rejections under 35 U.S.C. 102(b), it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). *See also Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied*, 469 U.S. 851 (1984). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989). When a reference is silent about an inherent characteristic, "such gap in the reference may be filled with recourse to extrinsic evidence." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). "Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Id.*

Additionally, before discussing the obviousness rejection herein, it is thought proper to briefly state what is required to sustain such a rejection. The issue under § 103 is whether the PTO has stated a case of *prima facie* obviousness. According to the MPEP § 2142, the Examiner has the burden and must establish a case of *prima facie* obviousness by showing some motivation in a prior art reference to modify that reference, or combine that reference with multiple references, to teach all the claim limitations in the instant application.

Applicants respectfully assert the Examiner has not satisfied the requirement for establishing a case of *prima facie* obviousness in this rejection.

The Examiner has rejected claims 11, 12, and 24-26 under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Winnik.

Rejection of Claim 11

Winnik does not describe each and every element of claim 11. For instance, Winnik does not teach or suggest using a convertible moiety in its hydrophobic form as required by claim 11. The Winnik reference does not expressly recognize the methacrylate monomers as being convertible, therefore the reference does not make a determination whether the monomers used in Winnik are in their hydrophobic or hydrophilic form. Additionally, Winnik does not teach the step of converting the convertible monomers from their hydrophobic to their hydrophilic form. The burden is on the Examiner to show where Winnik teaches both preparing amphipathic polymer particles comprised of unsaturated convertible monomers in their hydrophobic form and converting the convertible monomers into their hydrophilic form as now required by the claim. To avoid confusion, it is the Applicant's position that the product by process limitations make the composition different than that of Winnik. For example, by polymerizing while a convertible moiety is in hydrophobic form allows for a very homogenous hydrophobic mixture for polymerization, and further, by converting the moieties from hydrophobic form to hydrophilic form as described in the claim, hydrophilic groups can be included in the formed polymeric particles, but these groups do not interfere with polymerization. Thus, the structures formed by the enumerated product by process steps is necessarily different than the prior art.

Accordingly, the Applicant respectfully requests that the 102(b) rejections of claim 11 be withdrawn because Winnik does not teach each and every element of that claim. Additionally, it is requested that the 103(a) rejections be withdrawn as nothing in Winnik would make obvious to one of ordinary skill in the art the use of a convertible moiety in their hydrophobic form or the step of converting a convertible moiety into hydrophilic form. In other words, there are at least two elements missing from the teachings of Winnik, as set forth above, and there is no suggestion within the reference to modify this reference to arrive at the claimed invention.

### Rejection of claim 12

Due to the similarities between claim 11 and claim 12, the same arguments given in the discussion of claim 11 apply to claim 12. Additionally, claim 12 requires the presence of a polymerizable dye monomer, which is also not taught by Winnik. The dye used in Winnik is described as being “covalently attached to the resulting polymer backbone . . . .” Column 4, lines 41-42. The dye used in the instant invention must be a polymerizable dye monomer and is included in the polymerization reaction. The dye of the instant invention becomes integrated into the amphipathic polymer particles because it is involved in the polymerization reaction. In other words, rather than merely being covalently bonded to a surface of a resulting polymer backbone, the dye of the instant invention is incorporated into the actual polymer particles. Therefore, Winnik does not teach each and every element of claim 12 as required by 102(b). In addition, nothing in Winnik would make obvious to one of ordinary skill in the art using convertible moiety monomers in their hydrophobic form, converting the convertible moiety from its hydrophobic form to its hydrophilic form by changing the pH of the emulsion, or incorporating a polymerizable dye monomer into the amphipathic polymer particles. These product by process steps necessarily make the composition different than those cited in the prior art as described previously. For these reasons, the Applicant respectfully requests that the 102(b) and 103(a) rejections be withdrawn.

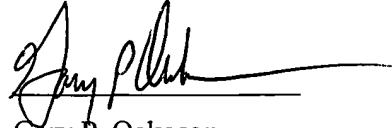
### CONCLUSION

In view of the foregoing, Applicant believes that claims 11 and 12 present allowable subject matter and allowance is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone Susan E. Heminger at (650) 236-2738 so that such issues may be resolved as expeditiously as possible.

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Dated this 7<sup>th</sup> day of June, 2006.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gary P. Oakeson", written over a horizontal line.

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